Coordination and Support Action (CSA) for the Big Data for Better Outcomes programme

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Big Data for Better Outcomes (BD4BO)
Initiative within IMI2

Goal
- Support the **evolution towards outcomes-focused and sustainable healthcare systems**
- **Exploit** medical innovation and opportunities offered by **large data sets** from variable sources

Themes/Enablers

1
Design sets of standard outcomes and demonstrate value

- Sets of target outcomes
- Clinical endpoints
- Alignment of HC stakeholders on the value of those outcomes

2
Increase access to high quality outcomes data

- Mapping of sources, methods and tolls for collection and harmonization
- Governance and technical standards

3
Use data to improve value of HC delivery

- Drivers of outcomes variation
- Best clinical practices
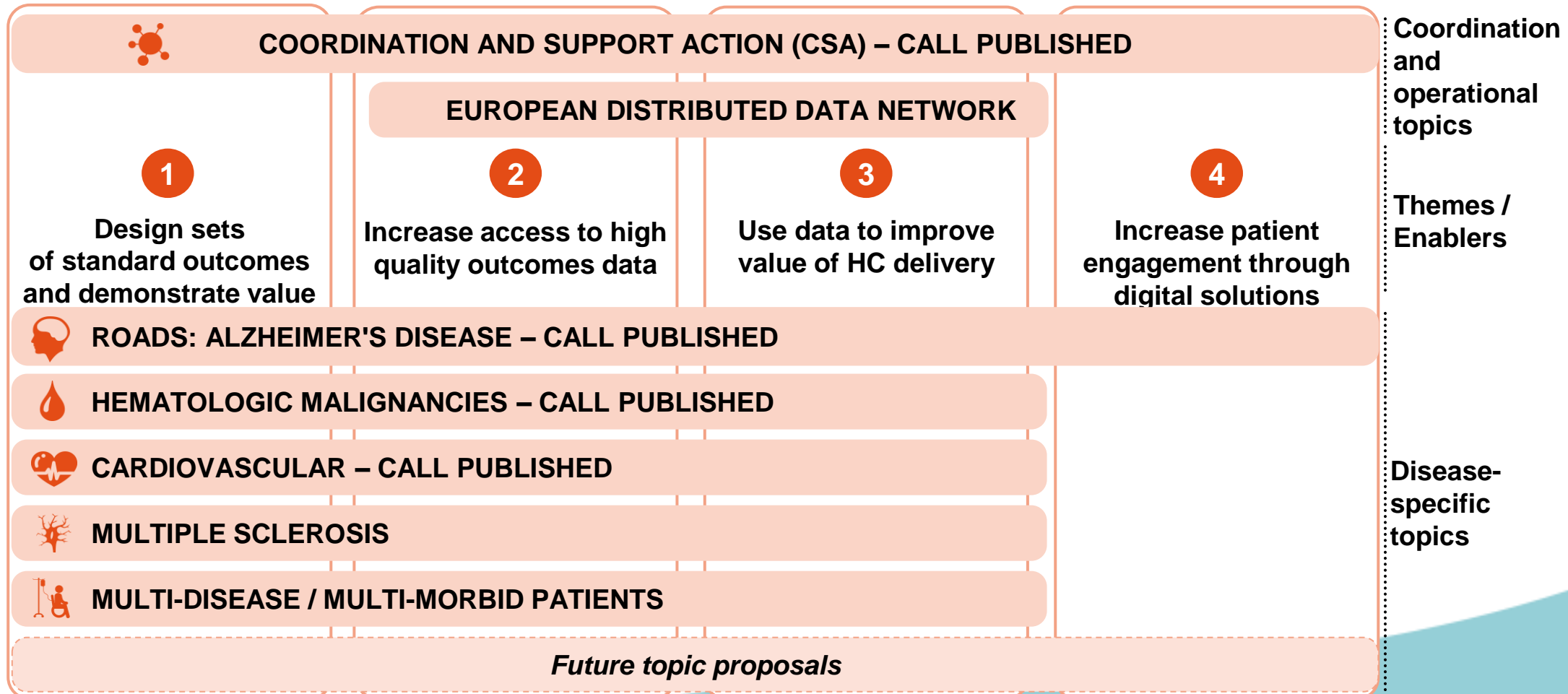- Methodologies to predict outcomes

4
Increase patient engagement through digital solutions

- Patient Reported Outcomes opportunities
- Profiling patients behaviors
- Tools to increase patient engagement

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BD4BO – Status

Goal: *Support the evolution towards outcomes-focused and sustainable healthcare systems, exploiting the opportunities offered by large and variable data sources*

COORDINATION AND SUPPORT ACTION (CSA) – CALL PUBLISHED

Coordination and operational topics

EUROPEAN DISTRIBUTED DATA NETWORK

1 Design sets of standard outcomes and demonstrate value

2 Increase access to high quality outcomes data

3 Use data to improve value of HC delivery

4 Increase patient engagement through digital solutions

Themes / Enablers

ROADS: ALZHEIMER'S DISEASE – CALL PUBLISHED

HEMATOLOGIC MALIGNANCIES – CALL PUBLISHED

CARDIOVASCULAR – CALL PUBLISHED

MULTIPLE SCLEROSIS

MULTI-DISEASE / MULTI-MORBID PATIENTS

Disease-specific topics

Future topic proposals

Such an ambitious Programme requires an efficient Coordination and Support Action (CSA) structure
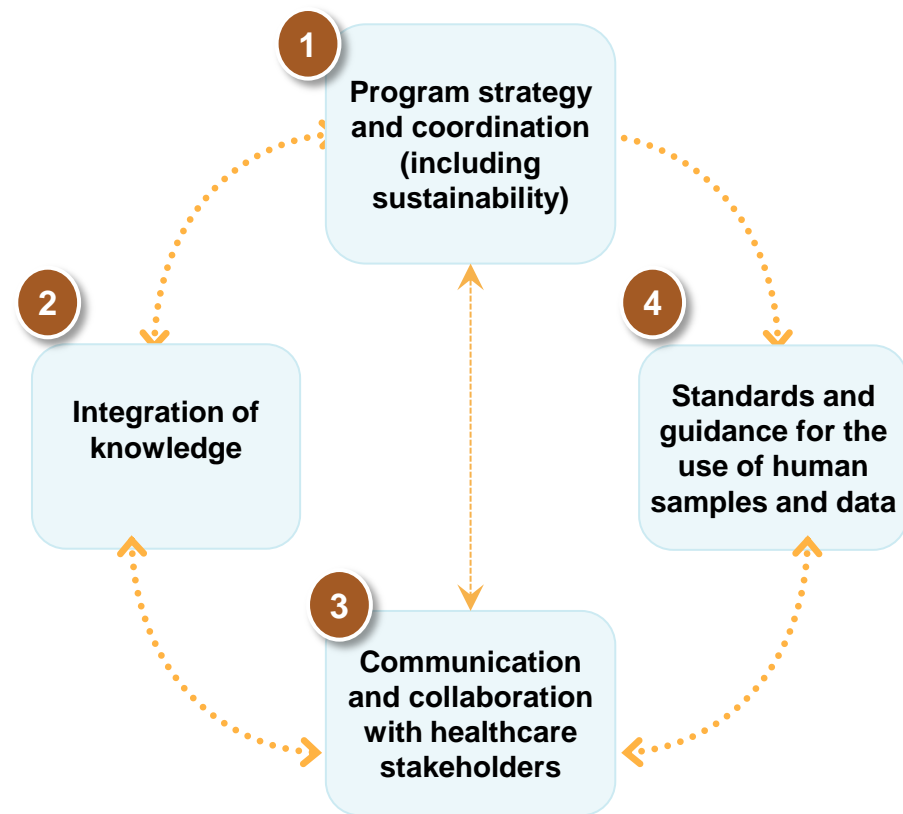
- Aligned **strategy**
  - Defined in close collaboration with key healthcare systems' stakeholders
  - Identifying the necessary enablers as well as barriers and opportunities to support healthcare systems transformation to more outcomes transparency

- Efficient **management of BD4BO initiative**
  - Coordination with minimal administration and shared commitment and accountability

- **Integration** of findings and communication of aggregate learnings

- Economies of scale: Relevant **expertise** shared across projects

- **Platform** for all projects to get access to relevant healthcare systems' stakeholders

BD4BO CSA at a glance

The Coordination and Support Action will:

- Drive Health Outcomes strategy of the programme

- Integrate knowledge and disseminate findings

- Design approaches to ensure sustainability of projects in the programme

- Ensure consistency and quality across projects

- Bring and share expertise across all diseases and themes

Coordination and Support Action (CSA)
Key themes to be addressed

1 Program strategy and coordination (including sustainability)

2 Integration of knowledge

4 Standards and guidance for the use of human samples and data

3 Communication and collaboration with healthcare stakeholders

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Need for public-private collaboration

- CSA engagement of patient groups, regulators, payers, HTA and health policy makers in addition to academics is essential
    - to ensure findings have appropriate buy-in and ultimately deliver real impact in transforming healthcare systems
    - To ensure proper data protection

- Collaboration between healthcare stakeholders and alignment with existing projects to define a governance framework for sharing data

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Objectives of the full project (1/2)

- Drive the health outcomes strategy of the BD4BO programme
    - Establish an enabling platform with relevant stakeholders to support the quality and consistency of the individual projects
    - Operationalise strategy to ensure quality / consistency across projects, identification of synergies and sustainability of results
    - Identify opportunities for additional research action projects
- Integrate knowledge from the projects and synthesize key learnings to generate evidence to support healthcare systems' transition to value based healthcare and increased health-outcomes focus
    - Ensure alignment with forthcoming 'Distributed Data Network' DDN project

Objectives of the full project (2/2)

- Act as centre of excellence to exchange knowledge and learnings across projects

- Disseminate/share aggregated learnings among all stakeholders to complement the activities of the disease specific projects within the Big Data for Better Outcomes initiative, stakeholders to include patient organizations, regulators, payers, HTA and healthcare policy makers in addition to academics

- Develop standards and guidance for the use of human samples and data in context of data privacy and related legal aspects

- Help address common issues

- Support the overall IMI objectives to reduce attrition, to allow faster access and to ensure better outcomes
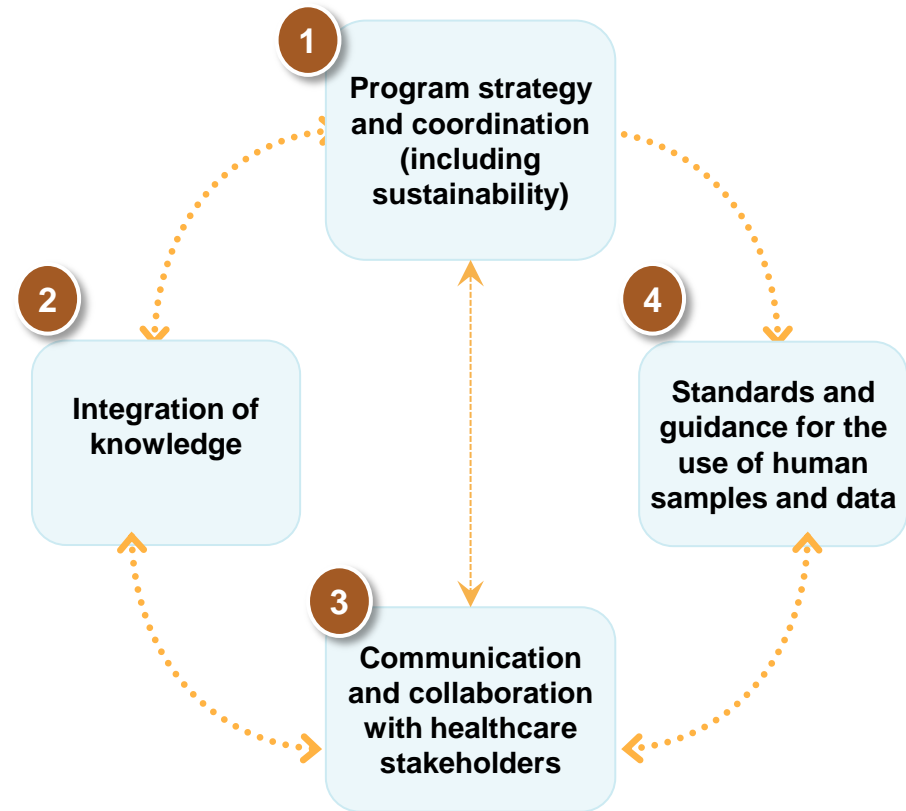
Pre-competitive nature

- The IMI design allows pharma companies to collaborate with academia, payer, regulatory, patient organisations and other important stakeholder partners to prepare health outcome data for health/social care and data systems as a base for discussion and decisions for support for health care system transition to value based healthcare and increased health outcomes focus

- Value based health care with increased health outcome focus is expected to allow a better use of scarce resources within the health care budgets of member states

Expected impact on the R&D process

- Comprehensive plan for the development of key enablers to support the evolution towards value based and more outcomes-focused sustainable healthcare systems in Europe, exploiting the opportunities offered by big and deep data sources
- Leveraging the outputs of other IMI data-related projects for the BD4BO objectives
- Optimisation of investment in individual research actions under the programme

Suggested architecture of the project (1/2)

- Four themes proposed to address all objectives
  - Development of a strategy
  - Enabling its implementation
  - Coordination of a programme
  - Standards for use of samples and data

- The applicants can suggest a similar or different architecture bearing in mind that public and private proposals and resources will be aligned at stage 2.

1 Program strategy and coordination (including sustainability)

2 Integration of knowledge

3 Communication and collaboration with healthcare stakeholders

4 Standards and guidance for the use of human samples and data

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Suggested architecture of the project (2/2)

- Proposed Work Themes

  1) Programme strategy and coordination (including sustainability)

  2) Integration of knowledge incl. knowledge repository

  3) Communication and Collaboration with Healthcare Systems Stakeholders

  4) Standards and guidance for the use of human samples and data

Work Themes 1-3 of suggested architecture

- WT 1 Overall Strategy
  - Programme management and coordination of projects
  - Consistency, synergies and sustainability of projects
- WT 2 Knowledge Management
  - Initial repository of knowledge
  - Definition of knowledge domains
  - Distillation of findings and synthesis of key learnings
- WT 3 Collaboration with Healthcare Systems Stakeholders
  - Dissemination of programme findings
  - Establishment of communication channels with key healthcare systems stakeholders

Work Theme 4 – Aims and Deliverables

- Main goal: Development of uniform minimum standards and potentially templates for:
  - Informed consent forms (ICF) to be used for clinical studies, for other studies such as preclinical studies, for donation of human biological samples of patients and healthy volunteers outside clinical studies
  - Complying with privacy regulations when conducting big data projects
- Deliverables:
  - Minimum standards/ICF templates for the use of clinical data and human samples
  - Guidance documents
    - ➤ to facilitate work with ICF and with Big Data
    - ➤ dealing with related common data protection issues such as terminology, applicability of data protection laws to human samples, cell lines, xenografts, pseudonymization vs. anonymization, data density, data protection mechanisms, patient information vs. informed consent
  - Training and educational guidance for BD4BO, IMI/IMI2 projects, non-IMI related addressees (e.g. patients)

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Work Theme 4 – Laws and Alignment

- Working basis:
  - EU General Data Protection Regulation
  - Local laws and standards
  - National and international data privacy initiatives (e.g. EFPIA Data Protection Working Group, CTTI, P-IWG, TransCelerate)
- Min. 7 European countries to facilitate harmonization incl. Germany, France, Spain and Italy
- Ensure in particular an appropriate collaboration with:
  - Academia and academic research groups
  - European bio-banking organisations, IT companies
  - Regulatory authorities dealing with data protection in healthcare
  - Patient organizations and medical associations

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Expected contributions of the applicants (1/2)

- In view of the importance of many stakeholders in today's biomedical research ecosystem, expert contributions from patient groups, regulators, payers, HTA bodies, academia, providers, healthcare policy makers appear essential for a meaningful impact of the CSA activities

- Knowledge and expertise in health care systems including definition of validated outcomes metrics and measurement tools to support value-based healthcare

- Knowledge and expertise in real world evidence (RWE) and outcomes measurement within regulators, HTAs, payers, providers, patient associations

- Expertise in data knowledge management to extract, analyse, aggregate and sustain large data sets and resulting knowledge

Expected contributions of the applicants (2/2)

- Knowledge and expertise in legal, ethics and data privacy aspects on the management of sensitive personal level data

- Ability to develop outreach and communication strategies, tools and materials on the role and challenges of using big data to improve outcomes, to the stakeholders and public at large

- Project management experience for initiatives of this complexity / scale, incl. risk management / sustainability of results

- The applicant consortium is expected to be multidisciplinary and to enable effective collaboration between key stakeholders with the ability to engage with extended audiences

- The size of the consortia shall be carefully considered by the applicants in order to balance multidisciplinarity and operational efficiency of the CSA

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Expected (in kind) contributions of EFPIA members

- Contribution of knowledge and expertise in the following areas:
  - HEOR, Health outcomes definitions, value-based healthcare, RWE, measurement tools and analytical
  - Regulatory/supervisory, HTA, payers, providers, patient groups incl. engagement via digital solutions
  - Benefit/risk assessment, pricing and reimbursement
  - Data privacy law and related legal aspects
  - Medical affairs and health care communication, website mgmt.
  - Data/knowledge management, repository of knowledge
  - Public policy and governmental affairs
  - Project and meeting coordination including an overall BD4BO platform

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What's in it for you?

- Regulatory/HTA/Payers/Policy Makers: Contribute and shape the generation of comprehensive outcomes evidence to establish a commonly accepted base for decision making on value based health care

- Patient Organisations: Definition of a minimum set of measurable patient relevant real world outcomes and digital patient engagement solutions

- Research: Develop recommendations on appropriate metrics and data categories for relevant health outcome data including RWE

- SMEs: Outline data strategies to collect and characterize health outcomes relevant for decision making in value based health care

Key deliverables of the full project

- Strategic drive and coordination of projects within "Big Data for Better Outcomes"

- Integration and management of knowledge from projects

- Communication and Collaboration with Healthcare Systems Stakeholders

    - Dissemination of aggregated findings

    - Establishment of communication channels with key healthcare systems stakeholders

- Standards and guidance for the use of human samples and data

Questions?

Contact the IMI Programme Office
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